IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

WALGREEN CO.; ECKERD CORPORATION; THE KROGER CO.; and MAXI DRUG, INC.,	:	
Plaintiffs,	:	CASE NO.
vs.	:	
ABBOTT LABORATORIES; FOURNIER INDUSTRIE ET SANTÉ; and LABORATORIES FOURNIER S.A.,	:	**DEMAND FOR JURY TRIAL**
Defendants.	:	

COMPLAINT

Plaintiffs Walgreen Co., Eckerd Corporation, The Kroger Co. and Maxi Drug, Inc. d/b/a Brooks Pharmacy (collectively "Plaintiffs") sue Defendants Abbott Laboratories, Fournier Industrie et Santé, and Laboratories Fournier S.A., and for their Complaint allege as follows:

Nature of the Action

1. This is a civil antitrust action seeking treble damages and other relief arising out of Defendants' unlawful monopolization of the market for fenofibrate, a drug used to lower cholesterol and triglycerides, which is manufactured and sold by Defendants under the brand name TriCor. As described in more detail below, Defendants have unlawfully delayed and impeded generic competition to TriCor by undertaking *two* expensive and unnecessary product conversions that were designed solely to switch users from one form of the drug to a different form of the drug in advance of the commencement of generic competition. These conversions had the purpose and effect of depriving generic competitors of a market for their products and thereby maintaining Defendants'

monopoly in the fenofibrate market. Defendants' unlawful conduct has deprived Plaintiffs and other purchasers of the benefits of generic competition from mid-2002 through the present.

Parties

2. Plaintiff Walgreen Co. ("Walgreen") is an Illinois corporation having its principal place of business in Deerfield, Illinois. Walgreen owns and operates retail stores in several states at which it dispenses prescription drugs to the public. During the relevant period, Walgreen purchased TriCor directly from Defendants. Walgreen brings this action on its own behalf and (with respect to certain purchases) as the assignee of a pharmaceutical wholesaler, AmerisourceBergen Corporation, which purchased TriCor directly from Defendants during the relevant period for resale to Walgreen.

3. Plaintiff Eckerd Corporation ("Eckerd") is a Delaware corporation having its principal place of business in Warrick, Rhode Island. Eckerd owns and operates retail stores in several states at which it dispenses prescription drugs to the public. During the relevant period, Eckerd purchased TriCor directly from Defendants.

4. Plaintiff The Kroger Co. ("Kroger") is an Ohio corporation having its principal place of business in Cincinnati, Ohio. Kroger owns and operates retail stores in several states at which it dispenses prescription drugs to the public. During the relevant period, Kroger purchased TriCor directly from Defendants.

5. Plaintiff Maxi Drug, Inc. d/b/a Brooks Pharmacy ("Brooks") is a Delaware corporation having its principal place of business in Warrick, Rhode Island. During the relevant period, Brooks either purchased TriCor directly from Defendants or purchased it from McKesson Corporation ("McKesson"), a pharmaceutical wholesaler, which purchased TriCor directly from

Defendants for resale to Brooks. Brooks brings this action in its own behalf and as McKesson's assignee.

6. Defendant Abbott Laboratories ("Abbott") is an Illinois corporation having its principal place of business in Abbott Park, Illinois. Abbott develops, manufactures and sells brand-name pharmaceutical products and other products in the United States and elsewhere.

7. Defendants Fournier Industrie et Santé and Laboratories Fournier, S.A. (collectively "Fournier") are French corporations having their principal place of business at 42 Rue de Longvie, 21300 Chenove, France.

Jurisdiction and Venue

8. This action arises under section 2 of the Sherman Act, 15 U.S.C. §2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. §§15(a) and 26. The Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§1331 and 1337(a).

9. Venue is proper in this Court pursuant to section 12 of the Clayton Act, 15 U.S.C. §22, because each Defendant is an inhabitant of this District or is found or transacts business there.

Trade and Commerce

10. The pharmaceutical products at issue in this case are sold in interstate commerce, and the unlawful activities alleged in this Complaint have occurred in, and have had a substantial effect upon, interstate commerce.

Operative Facts

Federal Regulation of New Pharmaceutical Products

11. Under the federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq.*, approval by the Food and Drug Administration ("FDA") is required before a new drug may be sold in interstate commerce. Premarket approval for a new drug must be sought by filing a new drug application with the FDA, under either section 355(b) or section 355(j) of the Act, demonstrating that the drug is safe and effective for its intended use.

12. In 1984, Congress amended the Food, Drug and Cosmetic Act by enacting the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Amendments or the Hatch-Waxman Act. Hatch-Waxman simplified the regulatory hurdles for prospective generic drug manufacturers by eliminating the need for generic companies to file lengthy and costly New Drug Applications ("NDAs") in order to obtain FDA approval. Instead, such companies are permitted to file Abbreviated New Drug Applications ("ANDAs") and to rely on the safety and effectiveness data already supplied to the FDA by the brand-name manufacturer. Hatch-Waxman also added a number of patent-related provisions to the statutory scheme, as described below. Congress's principal purpose in enacting the Hatch-Waxman Amendments was "to bring generic drugs onto the market as rapidly as possible." *Mova Pharmaceuticals Corp. v. Shalala*, 140 F.3d 1060, 1068 (D.C. Cir. 1998).

13. New drugs that are approved for sale by the FDA are sometimes protected by a patent or patents, which provide the patent owner with the exclusive right to sell that drug in the United States for the duration of the patent or patents involved, plus any extensions. Under 21 U.S.C. §355(b)(1), a patent holder seeking FDA approval for a new drug is required to "file with the FDA

the patent number and expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." Patent information received by the FDA with respect to approved drugs is published in a book entitled "Approved Drug Products With Therapeutic Equivalence Evaluations," commonly known as the "Orange Book," where it can be found and consulted by future FDA applicants.

14. Generic drugs are drugs which the FDA has found to be bioequivalent to brand name drugs. The first generic competitor to enter a market typically does so at a price at least 30% lower than the price of the equivalent brand-name drug and quickly takes a substantial amount of market share away from the brand-name manufacturer. As additional generic competitors come to market, the price of the generics continues to fall, and their combined market share continues to grow. In some cases, generic competitors sell products equivalent to brand-name prescription drugs for as little as 10% of the price of the brand-name drug, and have captured as much as 90% of the brand-name drug's pre-generic sales.

15. Brand-name drug manufacturers typically market their products using representatives known as "detailers" who visit physicians' offices in an effort to persuade physicians to prescribe their products. Generic drug manufacturers do not market generic products in this way, but instead rely on retail pharmacies to substitute generic drugs for brand-name drugs when a prescription is presented to the pharmacist. It is not practical or feasible for generic manufacturers to generate prescriptions for a generic drug in the same way that a brand-name manufacturer generates prescriptions for a brand-name drug.

16. The price competition engendered by generic drug manufacturers benefits all purchasers of the drug, who are able to buy the same chemical substance at much lower prices. Retail pharmacies, such as those owned and operated by Plaintiffs, substitute generic drugs for brand-name drugs wherever possible in order to lower their own costs and those of their customers.

Abbreviated New Drug Applications for Generic Drugs

17. Under Hatch-Waxman, a drug manufacturer may seek expedited FDA approval to market a generic version of a brand-name drug by filing an ANDA pursuant to 21 U.S.C. §355(j). An ANDA relies on the safety and efficacy data already filed with the FDA by the manufacturer of the equivalent brand-name drug.

18. An applicant filing an ANDA for a generic version of a brand-name drug must certify to the FDA that one of the following conditions is satisfied: (1) the brand-name manufacturer has not filed patent information with the FDA (a "Paragraph I certification"); (2) the patent or patents have expired (a "Paragraph II certification"); (3) the patent will expire on a particular future date, and the generic manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or (4) the patent is invalid and/or will not be infringed by the generic manufacturer's product (a "Paragraph IV certification"). 21 U.S.C. §355(j)(2)(A)(vii). If an unexpired patent has been listed in the Orange Book by the brand-name manufacturer, a generic applicant is required to file either a Paragraph III or a Paragraph IV certification.

19. If a generic manufacturer submits a Paragraph IV certification stating that a listed patent is invalid or will not be infringed, it must notify the patent owner of the filing and explain why the patent is invalid or will not be infringed. 21 U.S.C. §355(j)(2)(A)(vii)(IV).

20. The patent owner, upon receiving a Paragraph IV certification from an ANDA applicant, has 45 days in which to initiate a premarketing patent infringement action against the applicant (a cause of action created by Hatch-Waxman). If no action is initiated within 45 days, FDA approval of the generic proceeds without regard to patent issues. However, if a patent infringement lawsuit is brought within the 45-day window, the FDA is automatically barred from granting final approval to the generic applicant until 30 months after the patent holder's receipt of the Paragraph IV certification, unless the patent expires or is held invalid or noninfringed first. 21 U.S.C. §355(j)(5)(B)(iii). This automatic stay of FDA approval is triggered without regard to the merits of the patent holder's lawsuit.

21. The Hatch-Waxman Amendments and the federal regulations that implement them do not give the FDA authority to resolve issues of patent law. The FDA is required to accept as true information it obtains from patent holders, and to withhold its approval of new generic drugs whenever the patent holder presents a litigated dispute (whether genuine or not) regarding the validity or infringement of a patent.

22. One result of the statutory and regulatory provisions described above is that brand-name manufacturers have a strong incentive to obtain, list and enforce patents against prospective generic applicants even if the patent is ultimately held to be invalid or not infringed by the generic applicant's proposed generic drug. If a brand-name manufacturer is able to obtain a patent from the Patent and Trademark Office, list the patent in the Orange Book and bring actions under the Hatch-Waxman Act to enforce the patent, the brand-name manufacturer can effectively block the entry of generic competition for as long as it takes for the federal courts to determine whether the patent is valid and infringed. This delay, which is triggered without regard to the merit of the patent holder's

claim, can be worth hundreds of millions of dollars to the manufacturer of a successful brand-name drug.

23. A second result of these provisions is that generic applicants are dependent on the existence of an FDA-approved bioequivalent brand-name drug in order to take advantage of the simplified ANDA approval process created by Hatch-Waxman and successfully market a generic drug. If a generic applicant files an ANDA with respect to a particular brand-name drug (drug 1) and the manufacturer subsequently withdraws drug 1 from the market and replaces it with a slightly different drug (drug 2), the generic applicant can continue to pursue an ANDA for a generic version of drug 1 only by seeking and obtaining a determination from the FDA that drug 1 was not withdrawn for safety or effectiveness reasons. 21 C.F.R. §314.122. Even if the generic applicant is able to obtain such a determination, withdrawal of the bioequivalent brand-name drug will as a practical matter eliminate the market for the generic drug because physicians will stop writing prescriptions for a drug that is no longer on the market. Under these circumstances, the generic applicant's only real alternative is to start over and submit a new ANDA seeking approval to market a generic version of drug 2, which will add several years to the approval process and therefore delay the commencement of generic competition by several years.

TriCor (Fenofibrate)

24. TriCor is used to reduce high-levels of low-density lipoprotein cholesterol ("LDL-C"), sometimes referred to as "bad cholesterol," and triglycerides by promoting the dissolution and elimination of fat particles in the blood. TriCor also increases levels of high-density lipoprotein cholesterol ("HDL-C"), sometimes referred to as "good cholesterol," and reduces LDL-C in patients with primary hypercholesterolemia (high bad cholesterol) or mixed dyslipidemia (high bad

cholesterol and high triglycerides). TriCor is also effective at reducing triglycerides in patients with hypertriglyceridemia (high triglycerides). The active pharmaceutical ingredient in TriCor is fenofibrate.

25. Fenofibrate is a fibrate. Fibrates, statins, bile acid sequestrants, and niacin are categories of cholesterol-lowering drugs. Each of those categories addresses cholesterol conditions differently, each has different side effects (some more serious than others), and each has different efficacy profiles in (i) reducing LDL-C, (ii) raising HDL-C, and (iii) lowering triglycerides. A cholesterol-lowering drug from any of the four categories is not reasonably interchangeable with a drug from another of the categories, and in most cases two drugs within any of the four categories are not reasonably interchangeable with one another.

26. On January 23, 1990, the U.S. Patent and Trademark Office (the "PTO") granted Defendant Fournier's application for U.S. Patent 4,895,726 (the "'726 patent"). In its '726 Patent, Fournier claims a dosage form of fenofibrate containing a co-micronized mixture of particles of fenofibrate and a solid surfactant. A solid surfactant is a surface-active agent that interacts with the surfaces of poorly soluble substances, such as fenofibrate, to help them dissolve. A micronized substance is one that has been reduced in size to the micron size range.

27. In 1997, Fournier granted Abbott an exclusive license to the '726 patent in the United States. Abbott submitted separate NDAs for three strengths of branded fenofibrate capsules it intended to market. The FDA approved the TriCor 67mg capsule NDA on February 9, 1998, and the TriCor 134 mg and 200 mg capsule NDAs on June 30, 1999. Defendants brought each of these products to market shortly after receiving FDA approval, and sales of the capsule rose quickly to top $158 million by 2000, and $277 million in 2001.

Defendants' Wrongful Scheme to Delay Generic Competition

A. The Illinois Patent Litigation

28. On December 14, 1999, Novopharm Limited (which was subsequently acquired by Teva Pharmaceuticals USA, Inc. ("Teva")) filed an ANDA with the FDA requesting approval to market generic fenofibrate 67 mg capsules (the "Teva Capsule ANDA") before the expiration of the '726 patent. The Teva Capsule ANDA was later amended by Novopharm to request approval to market generic fenofibrate 134 mg and 200 mg capsules. In connection with the Teva Capsule ANDA, Novopharm certified under Paragraph IV that the proposed generic fenofibrate capsule did not infringe the '726 patent.

29. On May 9, 2000, Impax Laboratories, Inc. ("Impax") also filed an ANDA for fenofibrate capsules. Impax similarly sought approval to market its fenofibrate capsules prior to the expiration of the '726 patent, and accordingly certified under Paragraph IV that its product did not infringe the '726 patent, and duly and timely notified Abbott of its ANDA.

30. On or about April 7, 2000, August 18, 2000 and March 19, 2001, respectively, Defendants initiated a series of infringement actions in the United States District Court for the Northern District of Illinois, against Teva (and its subsidiary, Novopharm) and Impax, alleging that the generic drug manufacturers had infringed the '726 patent under 35 U.S.C. §271(e)(2) (collectively, the "Illinois Patent Litigation"). Under Hatch Waxman, these suits imposed 30-month stays on FDA approval of Teva's and Impax's generic products.

31. The FDA granted Impax tentative approval for Impax's fenofibrate capsules on February 20, 2002. However, Abbott's and Fournier's lawsuit triggered the automatic 30-month stay under Hatch-Waxman, preventing FDA from granting final approval to Impax's capsule ANDA.

32. On March 19, 2002, the Illinois district court granted Teva's motion for summary judgment of non-infringement of the '726 patent in the Illinois Patent Litigation. In so doing, the Court construed various elements of the '726 patent, and concluded that Teva's generic fenofibrate capsule product did not literally infringe the terms of that patent. The court also held that Abbott and Fournier were estopped from asserting a range of equivalents which might be construed to include Teva's generic fenofibrate product.

33. Teva subsequently received FDA approval to market its 67 mg, 134 mg and 200 mg capsules on April 9, 2002. While Teva received final approval for its 134 mg and 200 mg capsules on this date, and came to market shortly thereafter, Teva received only tentative approval for its 67 mg capsule. Thus, as a result of the stay, Teva was not able to launch its 67 mg capsule until September 3, 2002.

34. On March 26, 2003, the Illinois district court granted Impax's motion for summary judgment of non-infringement of the '726 patent based, *inter alia*, on Impax's assertion of collateral estoppel on the basis of the earlier summary judgment that had been granted in the Teva infringement actions. The FDA subsequently granted Impax final FDA approval to market its fenofibrate capsule products on October 28, 2003.

B. The First Exclusionary Conversion

35. Defendants knew that by merely filing the Illinois Patent Litigation within 45 days of receiving notice of the ANDA filings from Teva and Impax, they would prevent the FDA from granting final approval to Teva and Impax for up to 30 months, regardless of whether Defendants' patent suits had any merit. Thus, even though Defendants lost the Illinois Patent Litigation, Defendants knew that by using the regulatory delay triggered by the mere filing of those actions,

Defendants were able to delay competition from Teva's and Impax's generic fenofibrate capsule products for up to 30 months.

36. Defendants used the time they obtained under the regulatory scheme to shelter TriCor from effective generic competition by converting the market from capsules to tablets and then taking steps to eliminate remaining demand for fenofibrate capsules before the generic manufacturers could obtain FDA approval of their ANDAs.

37. Defendants' scheme was executed in a number of steps:

a. Defendants obtained FDA approval to market a TriCor tablet formulation (in 54 mg and 160 mg strengths) on September 4, 2001, while the Illinois Patent Litigation was still ongoing, and while the 30-month stays of Teva's and Impax's generic fenofibrate capsules were still in effect. Importantly, these tablets offered no benefits to consumers because they contained the same drug as the earlier-approved capsules and were therapeutically and bioequivalent to the capsules. Indeed, the standard view is that capsules are superior to tablets. However, in this case the tablets offered huge benefits to Defendants because, unlike the capsules, there were no pending ANDAs seeking approval to market generic versions of the new tablet formulation at this time.

b. Defendants then stopped all new sales of TriCor capsules, and directed their sales force to sell only TriCor tablets in the future, and to pressure doctors not to write prescriptions for the capsule product.

c. Defendants then removed the product code for the capsules from the National Drug Data File ("NDDF") maintained by First Data Bank, even though they were not obligated to do so. Absent the removal of the capsule code from the NDDF, doctors could have still written prescriptions for TriCor capsules, and such prescriptions could have been filled with an FDA-

approved generic capsule product. However, by removing the capsule code from the NDDF, Defendants rendered this code, to which generic capsules would have been compared, obsolete. Because generic fenofibrate capsules could not be referenced to a TriCor capsule code, and because Defendants removed TriCor capsules from the market, there was no longer a brand reference drug for generic fenofibrate capsules. Such removal impeded substitution of a generic fenofibrate product for a prescribed TriCor product.

d. Defendants' removal of the reference code in the NDDF for their capsule products also made it more expensive for patients to use a generic version of those capsules in the event that any doctors continued to write prescriptions for the capsules. Patients would be forced to pay higher co-pay amounts for generic capsules because of the absence of a reference code for Defendants' branded TriCor capsules. This is because, without a reference code in the NDDF for capsules, generic capsules would be treated as branded products rather than generic products for purposes of establishing co-pay charges to patients and reimbursement rates to retailers under prescription benefit plans.

e. To the extent that Defendants seek to justify these acts by claiming a desire to introduce a supposedly better or superior product, this justification fails because the new tablets provided no material benefits to consumers that the capsules did not already provide. Moreover, even if the new tablets had some benefit over the capsules (which they did not), such benefit could have been offered without eliminating demand for TriCor capsules and/or removing the capsule code from the NDDF. Had Defendants not acted to destroy the demand for capsules, doctors and patients would have more readily been able to weigh the relative benefits (and prices) of capsules versus tablets, and pick the formulation they preferred. Instead, by withdrawing their capsules from the

market and impeding generic substitution for prescriptions of the branded capsules, Abbott acted against patients' interests by creating confusion and preventing patients who were using the capsules from refilling or renewing existing prescriptions with capsules (including cheaper generic capsules). If Abbott were solely interested in providing additional medical options for patients, Abbott would not have taken the additional step of impeding the sale of generic capsules. However, since Defendants' true goal was to interfere with and impede, to the greatest extent possible, generic competition, the existence of any ongoing sale of generic fenofibrate would undermine Defendants' scheme.

38. Defendants invested significant resources in developing the 54 mg and 160 mg tablets. Then, Defendants invested significant resources in demonstrating to the FDA that the 54 mg and 160 mg tablets are bioequivalent to the already-approved capsule formulations. Specifically, Defendants sought to convince the FDA that the tablets were bioequivalent to the capsules, and to obtain approval for a new indication for the tablets, which was for "raising HDL-C levels in adult patients with Frederickson Types IIa and IIb dyslipidemia." In doing so, however, Defendants relied upon the same clinical studies that had been submitted in support of their NDA for the TriCor capsules. Thus, the studies submitted had been performed with the already approved formulations, not the tablet formulation for which Defendants were seeking approval. As the FDA Medical Officer reviewing Abbott's 54 mg and 160 mg tablet NDA noted, "[t]hese studies, however, were conducted with the standard and micronized formulation of fenofibrate. Therefore, the approvability of this application relied on the demonstrated bioequivalence between the tablet and older formulations of fenofibrate." Medical Officer's Review of New Drug Application, August 30, 2000 (available at http://www.fda.gov/cder/foi/nda/2001/21-203_Tricor_medr.pdf).

39. Hence, in obtaining approval for the 54 mg and 160 mg tablets, Abbott established that the bioavailability of two products did not differ significantly when the two products are given in similar dosages under similar conditions. After incurring all the expenses of researching and developing the 54 mg and 160 mg tablets, of submitting an NDA to the FDA in November 1999 and of supporting that application with multiple submissions to the FDA through September 2000, Defendants merely succeeded in getting approval for products that were equivalent to products Defendants already had on the market.

40. In addition, Defendants undertook the significant additional expenses of converting their manufacturing process to the tablet formulations. Defendants undertook the significant additional expenses of "detailing" doctors and marketing the tablet formulations to health care entities with the goal of switching prescriptions and prescribing habits from the capsule products to the bioequivalent tablet products, which Defendants brought to the market at the same price as the capsule products.

41. Since Defendants were already marketing bioequivalent products, the process of developing, approving, launching, and converting demand to the "new" tablet products would not likely have been anticipated to result in sufficient additional revenue to justify the significant associated expenses absent the impact of the conversion on potential generic competition. Absent the expected harm to generic competition resulting from introduction of the 54 mg and 160 mg tablet products, there would have been no reason for Defendants to have brought those products to market.

42. The purpose and effect of Defendants' strategy was to destroy (and/or severely limit) generic competition that otherwise would have existed in sales of fenofibrate capsules. By engaging in this "litigation and switch" scheme, Abbott and Fournier did not simply delay sales of generic

fenofibrate capsules; they took additional steps that had the purpose and effect of impeding those generic capsules from ever meaningfully competing with TriCor products, even once Impax and Teva were legally permitted to begin sales, by destroying any demand for fenofibrate capsules before Teva or Impax could enter the market.

43. As a result of Defendants' exclusionary conduct, Teva and Impax were denied the opportunity to effectively launch their generic fenofibrate products, and were excluded from the most efficient means of distributing their products. When Teva was finally able to launch its fenofibrate capsule (which remained bioequivalent to TriCor tablets but was much less expensive), Teva captured only 5% of the fenofibrate market. This is in stark contrast to the "generic erosion" normally observed upon the launch of a generic bioequivalent to a branded product, where generics typically capture from 40% to 80% (or more) of the brand's sales within the first year of launch. Thus, as a direct and proximate result of Defendants' overall scheme to monopolize, Defendants effectively destroyed generic competition that should have started in early 2002, and have improperly maintained a 95% share of the market for fenofibrate products that would otherwise have eroded substantially in the face of price competition from lower-cost generic products.

C. The Delaware Patent Litigation

44. Having successfully shielded their product (and monopoly profits) from generic competition, Defendants were quick to return to the same strategy when generic competitors once again threatened to enter the fenofibrate market. This time before this Court, Defendants executed their scheme of reflexively filing patent suits against generic competitors, regardless of the merit (or lack thereof) of such suits, while using the delay that resulted from these suits to convert the fenofibrate market to a product not susceptible to generic substitution.

45. In an apparent reaction to Defendants' successful conversion of the market from capsules to tablets, on or around June 17, 2002, Teva filed with the FDA an ANDA for its generic fenofibrate 54 mg and 160 mg tablets (the "Teva Tablet ANDA"), along with a Paragraph IV certification that the ANDA did not infringe the '726 patent, as well as two additional patents that Defendants had subsequently listed in the Orange Book as covering the TriCor tablets, U.S. Patent No. 6,074,670 (the "'670 patent"), which issued on June 13, 2000, and U.S. Patent No. 6,277,405 (the "'405 Patent"), which issued on August 21, 2001. On or around August 21, 2002, Teva gave notice to Defendants of the filing of the Teva Tablet ANDA and the Paragraph IV certifications made therein. Abbott received notice of Teva's initial ANDA filing on August 26, 2002.

46. Teva subsequently amended its ANDA, on July 29, 2003 and December 17, 2003, respectively, by filing two additional Paragraph IV certifications, one for U.S. Patent 6,589,522 (the "'552 patent") and one for U.S. Patent 6,652,881 (the "'881 patent"), shortly after Abbott listed each of these patents in the Orange Book as claiming TriCor. Teva duly served Abbott with notice of each of its certifications, which prompted additional infringement complaints filed within 45 days of this notice.

47. In three separate complaints filed in the United States District Court for the District of Delaware (later consolidated into a single action), Abbott alleged that Teva had infringed the five patents as to which Teva had filed Paragraph IV certifications. The first complaint, filed on October 4, 2002, alleged infringement of the '726 Patent, the '670 patent, and the '405 patent; the second complaint was filed on August 29, 2003, alleging infringement of the '552 patent, and the third complaint was filed January 22, 2004, alleging infringement of the '881 patent.

48. By virtue of the filing of the first and second complaints, Defendants imposed two successive 30-months stays under Hatch-Waxman, thus barring FDA approval of Teva's ANDA. The first 30-month stay was triggered by the first complaint filed (involving the '726, '670 and '405 patents), and it expired on February 26, 2005, 30 months after Abbott received Teva's first notice letter. The second 30-month stay was generated by the second complaint filed involving the '552 patent, and is set to expire in February 2006. Because (and only because) of the modifications to Hatch-Waxman made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Abbott is not entitled to a third stay based on the third complaint for infringement of the '881 patent.

49. Similarly, Impax also sought to enter the fenofibrate market in the United States by filing an ANDA for fenofibrate tablets in or around December 2002. In connection with this ANDA, Impax submitted Paragraph IV certifications that the ANDA did not infringe the '726, the '670 and the '405 patents. As they had against Teva, Defendants sued Impax, asserting infringement of the '670 and the '405 patents. The filing of the initial infringement case, on January 23, 2003, triggered an automatic 30-month stay of approval of Impax's Tablet ANDA by the FDA. The issuance and Orange Book listing of the '552 patent resulted in an additional infringement case against Impax, and an additional 30 month stay. The listing of the '881 patent resulted in yet another suit against Impax, but again, as in the case of the suits against Teva, there was no additional 30-month stay associated with that infringement suit.

50. On March 5, 2004, the FDA granted tentative approval to Impax's and Teva's tablet ANDAs, which means that the FDA has determined that these generic products are bioequivalent to TriCor tablets of the same dosage strength, and that Teva and Impax have satisfied all the other

regulatory requirements, such as demonstrating safety and efficacy, for the sale of their fenofibrate product in the United States. The tentative approvals by the FDA would have been final approvals but for the successive 30-month stays resulting automatically from Abbott's and Fournier's filing and maintenance of their patent infringement actions against Impax and Teva concerning the tablet ANDAs, because the FDA was legally precluded from granting final approval to Impax or Teva until the stays expire or until the various Delaware infringement actions were resolved in favor of the generic manufacturers. Both Teva and Impax have represented to this Court that, absent the 30-month stays, they would have received final approval on March 5, 2004, and would have entered the market shortly thereafter with 54 mg and 160 mg generic tablets.

51. If it had not been for the first exclusionary conversion, from capsules to tablets, Teva and Impax likely would not have submitted ANDAs for tablets and, even if they had, Defendants likely would not have filed the patent cases that kept Teva's and Impax's generic tablets off the market after March 5, 2004 because generic erosion would already have occurred. Thus, but for the first conversion, either the product would have been marketed exclusively in capsule form or, even if tablets had been introduced, generic versions of the tablet would have become available in early 2004.

52. The various infringement suits in Delaware against Teva and Impax were consolidated and/or coordinated before this Court (the "Delaware Patent Litigation"). The Delaware Patent Litigation was heavily litigated by and among Defendants, Teva and Impax, and trial was scheduled to begin on December 6, 2004. Defendants succeeded in getting this trial date pushed back six months to June 6, 2005, however, through the filing of the subsequent infringement actions related to the '552 patent. Then, with less than a month to go before trial, Abbott and Fournier

(having obtained the sought-after delay) voluntarily moved to dismiss all the pending Delaware infringement actions.

D. The Second Exclusionary Conversion

53. Defendants' intent to abandon the Delaware Patent Litigation reveals their true motive for commencing these actions in the first place – to provide Defendants once again with the time needed to convert the existing fenofibrate market to a formulation not threatened by generic competition. During the pendency of the Delaware Patent Litigation, Abbott and Fournier were planning another product switch, which was implemented in late 2004, more than eight months after the generic manufacturers received tentative approval from the FDA for their tablet ANDAs.

54. While the Delaware actions against Impax and Teva were ongoing, Defendants, on November 5, 2004, obtained approval for a new NDA for a different formulation of TriCor tablets in 48 and 145 mg strengths. Although this new version of the tablets may be taken without food, it contains the same medicine, and is indicated for the same uses, as the old formulation tablets. However, by virtue of the new strengths, a prescription written for these new tablets cannot be filled with a generic product approved by the FDA pursuant to an ANDA filed on the previously-approved, higher-strength tablets.

55. In a familiar pattern, Abbott and Fournier then began marketing their new TriCor products and stopped selling the 54 mg and 160 mg tablet dosage forms. Once there was no more supply of Defendants' 54 mg and 160 mg tablet formulations, Defendants removed the reference code in the NDDF for these formulations, impeding the substitution of branded TriCor with cheaper generic fenofibrate tablets.

56. Defendants' removal of the reference code in the NDDF for their 54 mg and 160 mg tablet formulations also made it more expensive for any patients to use Impax's or Teva's generic fenofibrate tablets in the event that any doctors continue to write prescriptions for the 54 mg or 160 mg fenofibrate formulations. Patients will be forced to pay higher co-pay amounts for generic 54 mg or 160 mg fenofibrate tablets because of the absence of a reference code for Abbott's and Fournier's TriCor 54 mg or 160 mg tablets in the NDDF. This is because, without a reference code in the NDDF for 54 mg or 160 mg tablets, Impax's and Teva's tablets would be treated as branded products rather than generic products for purposes of establishing co-pay charges to patients and reimbursement rates to retail pharmacies under prescription benefit plans.

57. Based on the previous experience of the switch from the capsule to tablet, it is likely that the supply of Abbott's and Fournier's 54 mg and 160 mg tablets formulation will virtually disappear approximately six months after the date Abbott and Fournier stopped marketing this formulation.

58. But for Defendants' anticompetitive conduct, the tablet formulations never would have been introduced (because generic capsules would have dominated the market, and the new tablets offered no material benefits over the capsules). Generic versions of Defendants' original capsules would have been introduced in 2002 and would have quickly captured the bulk of the fenofibrate market. Moreover, even if the tablets would have been introduced in any case, the generic manufacturers would have started selling their generic fenofibrate 54 mg and 160 mg tablets shortly after March 5, 2004, the date on which FDA granted tentative approval (and but for Abbott and Fournier's conduct would have granted final approval) to Impax's and Teva's tablet ANDAs. Defendants did not receive approval for their new formulation NDA until November of 2004, and

thus could not have started their second round of efforts to switch the market until that time. Thus, but for Defendants' conduct, Impax and Teva would have started selling their fenofibrate tablets roughly eight months before Abbott and Fournier could have started converting the market to their new tablet formulation.

59. Defendants' conduct was intended to prevent, and has in fact prevented, the writing of prescriptions for TriCor that can be filled with a cheaper generic alternative. In the future, this will mean that a pharmacist will not be presented with a prescription that would allow for substitution with a generic version of the 54 mg and 160 mg tablet formulations, should one become available.

60. In connection with their NDAs for TriCor capsules and for TriCor 54 mg and 160 mg tablets, Abbott and Fournier submitted data to the FDA showing that those products are safe and effective. By approving Defendants' NDAs for those products, the FDA determined that those products are, among other things, safe and effective. Importantly, Abbott and Fournier have not disclosed any health or safety concerns, or any other concerns, with their capsule formulation of TriCor that would justify pulling the product from the market and removing it from the NDDF. Similarly, Abbott and Fournier have not disclosed any health or safety concerns, or any other concerns, with their 54 mg or 160 mg tablet formulations of TriCor that would justify pulling those products from the market and removing their associated codes from the NDDF. Defendants' product conversions have been nothing more or less than a tactic to maintain their monopoly in sales of fenofibrate products in the United States and to preclude Teva and Impax from effectively competing in the fenofibrate market.

Effects of Defendants' Unlawful Conduct

61. Defendants' exclusionary conduct has delayed or prevented the sale of generic fenofibrate in the United States, and has unlawfully enabled Defendants to sell TriCor at artificially inflated prices. But for Defendants' illegal conduct, generic competitors would have been able to successfully market generic versions of TriCor capsules by April 9, 2002, and additional generic competitors would have entered the market thereafter. The tablet version of TriCor would never have been introduced. Even if tablets had been introduced, generic competitors would have begun marketing generic versions of TriCor tablets by at least March 5, 2004, and additional generic competitors would have entered the market thereafter.

62. Defendants' pattern and practice of reflexively filing Hatch-Waxman patent cases and using the resulting 30-month stays to convert the market to a new formulation that is not subject to generic competition, while simultaneously discontinuing the old formulation, is exclusionary and unreasonably restrains competition. To the extent that Defendants have any legitimate purpose for their conduct, that purpose could be served by means that are less restrictive of competition. Among other things, Defendants could have launched a new tablet product without taking affirmative steps to destroy the demand for the existing capsule product. Defendants' conduct has allowed, and continues to allow, them to maintain a monopoly and exclude competition in the relevant market, to the detriment of all fenofibrate purchasers.

63. Defendants cannot justify their conduct with any supposed consumer benefits, since the enormous cost savings offered by generic drugs outweigh any supposed benefit from the new formulations of TriCor, which benefits are illusory and/or could have been obtained without taking affirmative steps to destroy demand for fenofibrate capsules. Defendants= exclusionary motive is

also illustrated by their willingness to sacrifice profits as part of the market switch strategy: Defendants' decision to incur the extra costs necessary to change formulations was economically rational only if the change has the effect of excluding generic competition. Defendants' introduction of the 54 mg and 160 mg tablets, which were bioequivalent to Defendants' capsules, and which relied upon the same clinical studies as were used to support the capsule NDA, was itself anticompetitive. But for the impact on generic competition, Defendants would not have invested the resources necessary to bring the 54 mg and 160 mg tablets to the market. But for the impact on generic competition, it would not have been economically rational to invest in the process of developing the bioequivalent tablet formulation, seeking FDA approval of that formulation, changing the manufacturing process, and engaging in significant marketing efforts to switch the market from capsules to the equivalently priced tablets.

64. If manufacturers of generic fenofibrate had been able to enter the marketplace and effectively compete with Defendants earlier, Plaintiffs would have substituted lower-priced generic fenofibrate for the higher-priced brand-name TriCor for some or all of their fenofibrate requirements and/or would have received lower transaction prices on their remaining TriCor purchases.

65. As a result of Defendants' unlawful and exclusionary conduct, Plaintiffs (or their assignors) were forced to continue to purchase branded fenofibrate from Defendants at monopoly prices rather than generic fenofibrate from a generic manufacturer at much lower prices. Plaintiffs continue to be overcharged by paying higher prices for fenofibrate than would have prevailed in the absence of Defendants' unlawful conduct.

Relevant Product and Geographic Markets

66. The relevant product market is the sale of fenofibrate – i.e., TriCor (in its various formulations) and its AB-rated generic equivalents. The relevant geographic market is the United States. A firm that was the only seller of prescription drugs containing fenofibrate in the United States could and would impose a significant, non-transitory price increase without losing sufficient sales to render the price increase unprofitable, as demonstrated by Defendants' ability to charge supracompetitive prices for fenofibrate during the period in which Defendants have lacked generic competition.

67. During the relevant period, Defendants' share of the relevant market has been between 95% and 100%.

68. Defendants' unlawful actions were taken for the purpose of maintaining Defendants' dominant share of the relevant market and allowing them to continue to charge monopoly prices free of generic competition.

Antitrust Violation
Monopolization (15 U.S.C. § 2)

69. At all relevant times, Defendants possessed monopoly power in the relevant market.

70. During the relevant period, Defendants willfully and unlawfully maintained their monopoly power by engaging in exclusionary conduct that discouraged rather than encouraged competition on the merits. As explained in detail above, Defendants on two separate occasions engaged in a "litigation and switch" campaign, whereby they instituted Hatch-Waxman patent litigation against generic applicants and during the resulting 30-month stay of FDA approval (1) made expensive and unnecessary changes to the existing TriCor product, (2) actively converted the market to a new formulation of the product, (3) discontinued sales of the old formulation of the product, and (4) took affirmative steps to restrict demand for the old formulation of the product, all

for the purpose of depriving generic competitors of a market for their products. These product conversions had the effect of delaying the commencement of generic competition and, even after generic versions of TriCor became available, of severely restricting the usage of those products. Defendants' conduct was economically rational only because of its adverse impact on generic competition.

71. Defendants' actions, individually and collectively, were intended to suppress rather than to promote competition on the merits, and have had precisely the intended effect.

72. Plaintiffs (or their assignors) have been injured in their business and property by reason of Defendants' unlawful monopolization. Plaintiffs' injury consists of paying higher prices for fenofibrate than would have been paid in the absence of Defendants' illegal conduct. Plaintiffs' injury is injury of the type the antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

73. Defendants' violations threaten continuing loss and injury to Plaintiffs unless enjoined by this Court.

WHEREFORE, Plaintiffs pray for judgment against Defendants and for the following relief:

A. A judgment for three times the damages actually sustained by Plaintiffs, as determined by a jury;

B. A declaration that Defendants have violated the antitrust laws in the ways described above;

C. Permanent injunctive relief which enjoins Defendants from continuing their illegal conduct, and requires them to take affirmative steps to dissipate the effects of their prior violations;

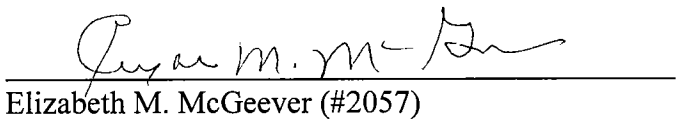
D. The costs of this suit, including a reasonable attorneys' fee; and

E. Such other and further relief as the Court deems just and proper.

Jury Demand

Plaintiffs demand a trial by jury of all issues so triable.

PRICKETT, JONES & ELLIOTT, P.A.



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